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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,817	02/22/2002	Komelia Polyak	00530-094001/ DFCI#689	3070

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225 FRANKLIN ST  
BOSTON, MA 02110

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/16/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/081,817	<b>Applicant(s)</b> POLYAK ET AL.	
	<b>Examiner</b> Gary B. Nickol Ph.D.	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

Claims 1-34 are pending.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 11, 26, drawn to isolated DNA, vectors, host cells, and methods of producing a polypeptide, classified in class 536, subclass 23.5; class 435, subclasses 69.1, 325, 320.1.
- II. Claims 8-10, and 25, drawn to isolated polypeptides, classified in class 530, subclasses 300,350.
- III. Claims 12-13, 15, drawn to an in-vitro method of inhibiting proliferation of a cancer cell, classified in class 435, subclass 4.
- IV. Claims 12, 14-15, 16, drawn to a method of inhibiting cancer cell proliferation in a mammal comprising administering a polypeptide, classified in class 424, subclass 184.1.

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- V. Claims 12, 14-15, 17, drawn to a method of inhibiting cancer cell proliferation in a mammal comprising administering a nucleic acid, classified in class 514, subclass 44.
- VI. Claims 12, 14-15, 18, drawn to a method of inhibiting cancer cell proliferation in a mammal comprising administering a recombinant cell, classified in class 424, subclass 93.2.
- VII. Claim 19, drawn to a method of identifying a compound that enhances inhibition of proliferation of cancer cells comprising adding test compounds to a plurality of cancer cells in conjunction with a known polypeptide, classified in class 435, subclass 4.
- VIII. Claims 20-21, as specifically drawn to a method of diagnosing whether or not a test cell is a cancer cell comprising measuring the mRNA expression of a HIN-1 gene, classified in class 435, subclass 6.
- IX. Claims 20, 22, as specifically drawn to a method of diagnosing whether or not a test cell is a cancer cell comprising measuring the level of HIN-1 polypeptides, classified in class 435, subclass 7.1.

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- X. Claims 23-24, as specifically drawn to a method of diagnosing whether or not a test cell is a cancer cell comprising determining the degree of methylation of a HIN-1 promoter region, classified in class 435, subclass 6.
- XI. Claims 27-29, drawn to monoclonal and polyclonal antibodies, classified in class 530, subclass 387.1, 388.1.
- XII. Claim 30, drawn to a method of identifying and treating a patient that has cancer comprising administering a compound that reduces methylation of the HIN-1 promoter region, classified in class 514, subclass 1.
- XIII. Claim 31, drawn to a method of identifying a compound that replaces the function of HIN-1 in cells that do not express HIN-1, classified in class 435, subclass 4.
- XIV. Claims 32-34, drawn to a method of identifying and treating a patient with cancer comprising administering to the patient a compound that induces expression of a gene with a methylated promoter region, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I-II, and XI represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects.

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The inventions of Groups III-X, XII-XIV are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The invention of Group I and the method of Group V are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the nucleic acid products as claimed can be used in a materially different process such as affinity chromatography.

The invention of Group II and the methods of Groups III-IV, VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the polypeptide products as claimed can be used in a materially different processes such as affinity chromatography, or methods of producing antibodies.

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The invention of Group XI and the methods of Groups III-X, XII-XIV are not at all related because the antibodies of Group XI are not used in any of the methods of Groups III-X, XII-XIV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the

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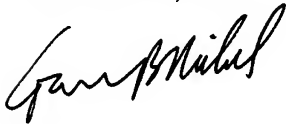
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organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.  
Examiner  
Art Unit 1642

GBN  
December 15, 2002

A handwritten signature in cursive script, appearing to read "Gary B. Nickol".